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The Food Safety People

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BY HAND

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 00D-1309; 65 FR 35376, Draft Guidance for Industry: Channels of Trade Policy for Commodities With Methyl Parathion Residues.

Dear Sir or Madam:

The National Food Processors Association (NFPA) provides the following comments on the draft document, "Guidance for Industry: Channels of Trade Policy for Commodities with Methyl Parathion Residues" (Guidance). NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks, and juices, or provide supplies and services to food manufacturers.

The food processing industry and NFPA member companies specifically will be directly affected by the manner in which the Food and Drug Administration (FDA) implements the Secretary's responsibilities under section 408(l)(5) of the Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA). While NFPA agrees with some elements of the Guidance, the compliance burden and uncertainties introduced by the Guidance are likely to cause disruptions in the distribution and sale of certain foods. The following comments address points for which NFPA seeks clarification as well as concerns about specific aspects of the guidance.

FDA's case by case approach to implementing 408(l)(5) with guidance to industry is appropriate.

With the Guidance, FDA addresses implementation of 408(l)(5) specifically for foods subject to the EPA proposed revocation methyl parathion tolerances. NFPA agrees that FDA should apply 408(l)(5) on a case by case basis by issuing specific

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guidance for the relevant foods affected by EPA revocation actions. The particular circumstances associated with the given EPA tolerance revocation(s) will influence FDA's

implementation of 408(l)(5). NFPA comments on EPA's proposed revocation of methyl parathion point out that revocation of pesticide tolerances for voluntarily canceled uses should not occur until treated foods that do not present an unacceptable dietary risk clear the channels of trade. If EPA were to allow the channels of commerce to clear with a tolerance in place, FDA's guidance would clearly be affected.

The chemistry of a pesticide and the nature and reliability of information about the fate of a pesticide residue on treated foods will also have implications for FDA's guidance. FDA should recognize that foods stored at ambient temperatures, under refrigeration or frozen might not always be the appropriate way to categorize foods for the purpose of developing channels of trade policy guidance.

FDA's presumptive approach for determining if foods have been legally treated is appropriate, but information gaps or limits should be described.

NFPA agrees with FDA's use of the fate and dissipation rates of methyl parathion to establish time frames for which methyl parathion will be presumed to be legally applied if a residue is found. However, including a more detailed description of the scope of the information provided by EPA is suggested. Interested parties could benefit from knowing if information gaps or limitations in the information exist. If additional information is needed, the opportunity for affected parties to provide such information should be given. For example, the Guidance document should include a listing of the specific commodity/storage forms that were in the 1999 EPA residue dissipation chart as well as the methodology and factors that EPA used to calculate the dissipation rates.

FDA should accommodate the application of methyl parathion between the effective date of the revocation of US tolerances and December 31, 1999 that is authorized in other countries.

NFPA agrees with FDA's presumption concerning the legal application of methyl parathion on domestically produced foods that are found to contain a methyl parathion residue until December 31, 2000. NFPA questions, however, if these exact conditions can be equally applied to foreign produced commodities without causing significant trade disruption.

FDA indicates that methyl parathion could not be legally applied after December 31, 1999 to foreign grown crops that are subject to use cancellations under FIFRA. This is based on the determination that FIFRA applies to the use of pesticides in other countries. NFPA is concerned that foods to which methyl parathion was legally applied in the

country of production and at a time when the U.S. tolerances were in effect, will not satisfy FDA's Guidance. Non-compliance is very possible, given FDA's determination that methyl parathion residues can be found on foods stored at ambient conditions for as long as 9 months and on refrigerated foods for a long as 12 months. This may lead to food processors being unable to purchase compliant commodities from foreign sources because methyl parathion was applied between December 31, 1999 and the final date of the revocation of US tolerances. Of greater concern is the potential that FDA's application of FIFRA use cancellations to other countries will lead to foreign governments establishing pesticide use conditions as well as residue tolerances or maximum residue limits for US produced foods. FDA should recognize that methyl parathion may be applied under the legal requirements of other countries between December 31, 1999 and the effective date of the revocation of US tolerances.

FDA should clarify "responsible party" and the implications for how the Agency's enforcement discretion will be applied.

FDA identifies general segments of the food industry that may be held as "responsible parties" including growers, brokers, and processors. In the statement of purpose FDA states the Guidance applies to firms in the food production and processing industries who handle food products. The "responsible party" could be interpreted to be the firm/entity that is identified as possessing the food when a methyl parathion residue is found. A discussion of whether FDA intends to identify retail grocers, as the "responsible party", would help clarify what information/documentation is needed by whom and on what time frame. For example, if FDA were to find a methyl parathion residue that triggers the need to demonstrate legal application on a food taken from a grocery store, does the Agency expect the grocery store to be able to produce appropriate documentation or would the manufacturer/supplier be considered the "responsible party"? NFPA is concerned that retail grocers may choose to refuse foods, particularly frozen foods or foods with a frozen ingredient, that may have been legally treated with methyl parathion rather than assume the burden of maintaining documentation and testing programs for demonstrating that methyl parathion was legally applied.

FDA should simplify the burden of demonstrating legal application of methyl parathion in situations involving foods with multiple ingredients.

Under the description of "Category II" documentation, FDA addresses the situation in which methyl parathion is found on a food that is the blend of different ingredients. FDA indicates that the responsible party will be expected to not only demonstrate that methyl parathion was legally used on an ingredient subject to 408(l)(5) but also demonstrate that the ingredient(s) not subject to 408(l)(5) did not receive methyl parathion applications. Further, FDA indicates the responsible party will be expected to have analytical results as evidence methyl parathion was not applied. This approach inappropriately complicates the application of 408(l)(5) by requiring analytical proof, at the level of the smallest production unit (e.g. a lot), that methyl parathion was not applied. The requirement for

extremely burdensome and unnecessary residue monitoring of all ingredients that were previously covered by a methyl parathion registration is implied. NFPA believes the multi-ingredient scenario described by FDA can be addressed in a more appropriate and reasonable way.

If a residue is found on a mult-ingredient product and the responsible party is able demonstrate that the likely source (e.g. a frozen ingredient) of the residue satisfies the Guidance, FDA should presume 408(l)(5) conditions are met unless there is some evidence to the contrary. This presumption could be confirmed with "Category I" or like documentation. The condition that analytical results will be needed to demonstrate methyl parathion was not illegally applied establishes a higher burden of proof than is applied in other scenarios described by FDA.

FDA guidance on the analytical method(s) that may be used to determine if a methyl parathion residue is present in a food for purposes of invoking section 408(l)(5) is suggested.

Section 408(l)(5) places FDA and the regulated community in a new enforcement environment. Under Section 408(l)(5) a detectable residue can mean FDA as well as the responsible party must devote resources to establishing the legal status of a food. Prior to 408(l)(5), a pesticide residue was either legal because it was within EPA's established tolerance or illegal because the residue was over tolerance or because no tolerance was established. The detection of a residue subject to 408(l)(5) will have new resource implications for both FDA and the responsible party. Some indication of the analytical method(s) FDA recognizes for determining if a methyl parathion residue is present would be extremely useful, particularly for those potentially responsible parties that choose to initiate or modify an analytical program for monitoring or establishing compliance.

Conclusion

NFPA appreciates FDA's effort to implement FFDCA Section 408(l)(5) in a manner that is reasonable and in keeping with the statutory requirements. However, the Guidance demonstrates the complexity of the task and will likely add substantial burdens and uncertainty for FDA as well as the food industry. Unfortunately, the result may be disruptions in the sale and distribution of foods as potentially responsible parties minimize the burden and uncertainty of satisfying conditions of the Guidance by deciding not to purchase foods that may have a methyl parathion residue even if the pesticide was legally applied.

Regards,

Rick Jarman

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